

continuous delivery of a single level of positive air pressure. A back-up rate feature enables the device to automatically switch between the two levels of pressure at pre-determined intervals. The original manufacturer of bi-level respiratory assist devices submitted documentation to us as part of its HCPCS coding recommendation. The manufacturer stated the following in the documentation:

- The word "intermittent" refers to devices that are designed to be used by the patient for only part of the day, usually during the hours of sleep.
- The bi-level equipment requires very little maintenance and servicing.
- Other than monthly replacement of the air inlet filter on the front of the system, there is no routine maintenance required.
- Recommends that a performance verification be performed after each year of operation to ensure that the device is functioning properly.

In accordance with OBRA of 1993, intermittent assist devices are excluded from the FSS payment category and, therefore, fall into the CR payment category.

On January 1, 1992, code E0453 with the description of "therapeutic ventilator; suitable for use 12 hours or less per day" was added and became effective in the HCPCS. This code was added to describe ventilators that are used on a part time basis by patients who are dependent on volume ventilators (HCPCS code E0450) for more than 12 hours a day. The premise behind the therapeutic ventilator (code E0453) is similar to the portable oxygen equipment. The stationary volume ventilator (E0450), like stationary oxygen equipment, would be the primary equipment used by the patient. The portable therapeutic ventilator, like portable oxygen equipment, would be used part of the day by the patient to move about in order to exercise muscles, prevent decubitus ulcers, and achieve other therapeutic goals. Therapeutic ventilators were properly classified in the FSS payment category.

Beginning as early as May 25, 1992, some Medicare carriers issued erroneous guidance to suppliers that intermittent assist devices with a back-up rate should be billed for using the HCPCS code E0453 for therapeutic ventilators (FSS payment category) instead of the HCPCS code E0452 for intermittent assist devices (CR payment category). We are not certain to what degree carriers and suppliers were using code E0453 as opposed to code E0452 to bill for intermittent assist devices with a back-up rate. However, this practice continued to some extent

through 1993 and 1994, the respective years in which the OBRA of 1993 change in payment categories for intermittent assist devices was enacted and implemented. Responsibility for processing DME claims was transferred during this time from 34 local carriers to 4 regional carriers known as Durable Medical Equipment Regional Carriers (DMERCs). The DMERCs also issued erroneous guidance to suppliers that the intermittent assist devices with a back-up rate should be billed for using code E0453 instead of code E0452.

The classification of intermittent assist devices with a back-up rate under the FSS payment category versus the CR payment category results in a substantial increase in Medicare payments. For example, comparing cost of E0453 over 5 years using the 2000 fee schedule ceiling of \$612.52, total Medicare payments under the FSS payment category would be \$36,751.20 after 5 years as opposed to \$7,778.99 if the device was classified under the CR payment category.¹ Based on retail prices we obtained, we determined for the year 2000, that the purchase prices for intermittent assist devices with a back-up rate range from approximately \$3,000 to \$6,000. This highlights the fact that the correct classification of these devices for Medicare payment purposes is a significant issue in terms of safeguarding the Medicare trust fund. That is, placing these devices in the FSS payment category instead of the CR category results in Medicare paying every 5 years approximately \$36,700 rather than \$7,700 for an item that can be purchased for \$6,000 or less.

In 1998, for the first time, the DMERCs conducted an in-depth review of the use of intermittent assist devices with CPAP. As a result, in July 1998, the DMERCs issued proposed medical review policies on intermittent assist devices with CPAP, which called for a revision to the HCPCS codes for these devices and the adoption of more specific nomenclature to describe respiratory assistance technology. The term "respiratory assist device, bi-level pressure capability" was proposed to replace the HCPCS wording of "intermittent assist device with CPAP," and separate HCPCS codes were proposed to differentiate between devices with a back-up rate and devices without a back-up rate.

¹ The CR payment of \$7,778.99 includes the 15 monthly rental payments plus 7 payments of \$61.25 for maintenance and servicing that can be billed every 6 months beginning 6 months after the 15th rental payment has been made.

C. Public Meeting on Payment for Respiratory Assist Devices

During the course of reviewing the DMERC medical review policies on respiratory assist devices, we became aware that the carriers and DMERCs had been allowing HCPCS code E0453 to be used primarily for the billing of respiratory assist devices with a back-up rate. As a result, we intended to take action to clarify that these devices belonged in the CR payment category. Because of concerns raised by the industry on the appropriate coding and payment classification for these devices, we announced in the **Federal Register** on June 4, 1999 that a public meeting would be held on June 25, 1999 to get input from the supplier community regarding the appropriate DME payment category for respiratory assist devices with a back-up rate. We made presentations at the June 25, 1999 public meeting, in addition to the Food and Drug Administration, the National Institutes of Health, respiratory assist device manufacturers, suppliers, clinicians, beneficiaries, and others.

The testimony at the public meeting that was given to support the claim that there is a need for FSS of respiratory devices with bi-level capability and a back-up rate described the need to have a respiratory therapist visit the beneficiary to make sure that the device is being used appropriately by the beneficiary and that the beneficiary is complying with the treatment. After the respiratory therapist performs an assessment of the beneficiary and has consulted with the beneficiary's physician, it may be determined that the pressure setting on the equipment needs to be adjusted. However, no information was presented at the public meeting that would indicate that the equipment itself requires FSS as required by section 1834(a)(3)(A) of the Act.

The DMERC medical review policies on respiratory assist devices were implemented on October 1, 1999. The following HCPCS codes were added as part of these new policies:

K0532 Respiratory Assist Device, Bi-Level Pressure Capability, Without Back-up Rate Feature, Used With Noninvasive Interface, E.G., Nasal Or Facial Mask (Intermittent Assist Device With Continuous Positive Airway Pressure Device)

K0533 Respiratory Assist Device, Bi-Level Pressure Capability, With Back-up Rate Feature, Used With Noninvasive Interface, E.G., Nasal Or Facial Mask (Intermittent Assist Device With Continuous Positive Airway Pressure Device)